Complete Summary

GUIDELINE TITLE

Common breast problems.

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Common breast problems. Ann Arbor (MI): University of Michigan Health System; 2007 Oct. 10 p. [7 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Common breast problems:

- Palpable mass or asymmetry
- Breast pain with negative exam
- Nipple discharge without abnormal exam findings
- Risk for breast cancer

GUIDELINE CATEGORY

Diagnosis
Evaluation
Management
Risk Assessment

Screening
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

- To identify appropriate evaluation and management strategies for women who present with four common breast problems
- Identify appropriate indications for referral to a breast specialist

TARGET POPULATION

Adults age 18 and older (non-pregnant)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis/Evaluation/Risk Assessment/Screening

1. Inspection and palpation with clinical breast exam (CBE)
2. Mammography
3. Ultrasound
4. Adjunctive magnetic resonance imaging (MRI)
5. Fine needle aspirate (FNA) with or without fluid cytology, as appropriate
6. Risk assessment using the National Cancer Institute's (NCI's) Breast Cancer Risk Assessment Tool
7. Referral to a breast specialist

Management/Treatment

1. Nonpharmacologic interventions to reduce breast pain, such as a well fitting bra, relaxation techniques, warm compresses or cold packs, gentle massage and a diet low in fat
2. Changes in current dose or in current medication
3. Pharmacologic treatment for breast pain including evening of primrose oil, diclofenac gel, non-steroidal anti-inflammatory drugs (NSAIDs), and hormonally active medicines including progesterone, Danazol, and Bromocriptine
4. Management of women at high risk for breast cancer including:
    - Counseling

- Risk reduction therapy including Tamoxifen, Raloxifene, and Tamosifen
- Referral to specialist to discuss genetic testing, as well as surgical options such as prophylactic mastectomy or oophorectome or participation in risk reduction trial

MAJOR OUTCOMES CONSIDERED

- Positive predictive value, sensitivity and/or specificity of diagnostic tests
- Incidence of breast cancer

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The literature searches for this update began with the results of the literature searches performed for the earlier version of this guideline through June 2000. For this update the Breast Cancer Screening and Diagnosis Guidelines of the National Comprehensive Cancer Network (2004) and its supporting literature through early 2004 were used to address the topics of nipple discharge, palpable mass, and screening of high risk women. The topics of breast pain and galactorrhea were used as major key words in separate MEDLINE searches of literature published from 1/1/99 through 5/31/05 in English for adult women with additional key words of guidelines and controlled trials.

The searches were supplemented with recent clinical trials known to expert members of the panel. The search was single cycle.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Conclusions were based on prospective randomized clinical trials if available, to the exclusion of other data. If randomized clinical trials (RTCs) were not available, observational studies were admitted to consideration. If no such data were available, expert opinion was used to estimate effect size.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The guideline was reviewed at clinical conferences or grand rounds meetings of divisions and departments to which the content is most relevant. This guideline was reviewed at meetings of Family Medicine, General Medicine, Radiology/Breast Imaging, and Surgical Oncology/Breast Care. The revised document is reviewed by the Guidelines Steering Committee, composed of representatives from all primary care specialties. The UMHS Executive Committee on Clinical Affairs performs a final review prior to institutionally endorsing the guideline.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Note from the National Guideline Clearinghouse (NGC): The following key points summarize the content of the guideline. Refer to the full text for additional information, including detailed information on evaluation and imaging techniques,

specific breast signs and symptoms, assessment and management of women of high risk women, and the anxious patient. Definitions for the levels of evidence (A, B, C, D) are provided at the end of the "Major Recommendations" field.

Palpable Mass or Asymmetry (See Figure 1 in the original guideline document)

- Discrete solid masses have a medium to high index of suspicion because physical exam cannot be a reliable tool to rule out malignancy.
    - Breast imaging is the best diagnostic approach.
    - Fine needle aspiration (FNA) by a qualified practitioner is an acceptable diagnostic tool, though if it precedes imaging it may disrupt tissue and affect mammography sensitivity. If aspiration reveals cyst, send fluid for cytology if it is bloody, if mass does not resolve completely with aspiration, or if cyst is recurrent in same location. A definitive report of fibroadenoma by fine needle aspiration requires no further workup. Masses not reported as definitive fibroadenomas or cysts should be evaluated by a breast specialist.

  Follow up physical exam after imaging or FNA is important. Cysts that recur are more likely to be malignant, and any nondiagnosed mass that persists should be evaluated by a specialist whether imaging has detected it or not.

- A non-discrete possible mass or thickening has a lower index of suspicion and should be reexamined in 1-2 months, preferably the week after menses in premenopausal woman. If a localized area remains abnormal on repeat exam then workup for possible malignancy is indicated, with diagnostic imaging and referral to a breast specialist. Persistent asymmetry, especially in postmenopausal women, is more suspicious than asymmetry that varies with the menstrual cycle *[D]*.
- Referral to breast care specialist is recommended for: (a) any suspicious mass, (b) any mass that is undiagnosed after diagnostic imaging, or (c) any woman at very high risk for breast cancer *[D]*.

Breast Pain - Negative Exam (See Figure 2 in the original guideline document)

- If physical exam and appropriate breast imaging are negative, the likely diagnosis is benign cyclic or noncyclic mastalgia: reassure patient. Trial of evening primrose oil (1000 mg twice a day [bid] for 3-6 months (or its active ingredient, gamma linoleic acid 160 mg bid) is reasonable *[A]*. Topical diclofenac gel is also promising for mastalgia *[A]*. Recommendation for a well-fitted bra is often helpful *[C]*.
- If persistent or localized pain not responsive after 2 to 3 months of conservative treatment, refer to breast specialist *[C]*.

Nipple Discharge Without Abnormal Exam Findings (See Figure 3 in the original guideline document)

- If discharge is serous or sanguinous, or if other risk factors are present (spontaneous discharge, single duct discharge), refer to breast specialist *[C]*.

- If discharge is not suspicious. If clearly galactorrhea, pursue medical workup and do not refer to breast specialist *[D]*. If discharge is from multiple ducts and gray to green in color do not refer to a breast specialist unless patient requests referral for symptomatic relief.

Assessment and Management of Women at High Risk for Breast Cancer

Primary care providers (PCPs) should identify and counsel women regarding breast cancer risk. Breast cancer screening frequency for high risk women is in Table 4 in the original guideline document. Women at high risk (5 year risk >1.7%) according to the National Cancer Institute (NCI) Breast Cancer Risk Assessment Tool (http://www.cancer.gov/bcrisktool/) should be:

- Offered referral to breast specialist, if available
- Considered for risk reduction therapy if appropriate candidate and with appropriate follow up

Definitions:

Levels of Evidence

A. Randomized controlled trials
B. Controlled trials, no randomization
C. Observational trials
D. Opinion of expert panel

CLINICAL ALGORITHM(S)

The following clinical algorithms are provided in the original guideline document:

- Palpable Breast Mass or Asymmetry: Diagnosis and Treatment
- Breast Pain Diagnosis and Treatment
- Nipple Discharge Diagnosis and Treatment (no mass)

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations" field).

Conclusions were based on prospective randomized clinical trials (RCTs) if available, to the exclusion of other data. If RCTs were not available, observational studies were admitted to consideration. If no such data were available, expert opinion was used to estimate effect size.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate evaluation and management strategies for women who present with common breast problems

POTENTIAL HARMS

- Mammography as a diagnostic tool may result in false negatives, especially in younger women. Overall, 10% of diagnostic mammograms are false negatives, with approximately twice the rate for younger women and half that rate for women over age 65.
- While magnetic resonance imaging (MRI) increases sensitivity compared to mammography alone in women at highest risk for breast cancer, it does so at the cost of decreased specificity and an increased need for invasive diagnostic procedures.
- For evaluation of solid masses, or nonpalpable masses detected by mammography, the sensitivity of fine needle aspiration (FNA) is variable, primarily dependent on the skill of the aspirator. Estimates of false negatives range from 1% to 35% for palpable lesions and up to 68% for nonpalpable lesions.
- Side effects of hormonally active medicines tend to limit their tolerability
- Risks and adverse side effects of Tamoxifen include increased incidence of endometrial cancer, deep venous thrombosis, potential increase in cataract formation, and increased liver enzymes. In perimenopausal women, hot flashes generally occur and there is a potential for adverse effect on bone density.
- The risk of lower extremity deep vein thrombosis (DVT) was increased with both Raloxifene and Tamoxifen; stroke risk was equal. The risk of adverse events with both interventions increases with a woman's age.

CONTRAINDICATIONS

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Absolute contraindications of Tamoxifen and Raloxifne include history of deep venous thrombosis or pulmonary embolism, thrombotic stroke, transient ischemic attacks, or pregnancy/pregnancy potential.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

These guidelines should not be construed as including all proper methods of care or excluding other acceptable methods of care reasonably directed to obtaining the same results. The ultimate judgment regarding any specific clinical procedure or treatment must be made by the physician in light of the circumstances presented by the patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Patient Resources
Staff Training/Competency Material

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

University of Michigan Health System. Common breast problems. Ann Arbor (MI): University of Michigan Health System; 2007 Oct. 10 p. [7 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Oct

GUIDELINE DEVELOPER(S)

University of Michigan Health System - Academic Institution

SOURCE(S) OF FUNDING

University of Michigan Health System

GUIDELINE COMMITTEE

Breast Care Guideline Team

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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None of the members of the Breast Problems Guideline Team have relationships with commercial companies whose products are discussed in this guideline. (The members of these teams are listed on the front page of this guideline.)

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available for download in Portable Document Format (PDF) from the University of Michigan Health System Web site.

AVAILABILITY OF COMPANION DOCUMENTS

Continuing Medical Education (CME) information is available from the University of Michigan Health System Web site.

PATIENT RESOURCES

The following are available:

- Benign breast disease. University of Michigan Health System; 2006 Oct. Various p. Available from the University of Michigan Health System Web site.
- Galactorrhea. University of Michigan Health System; 2006 Oct. Various p. Available from the University of Michigan Health System Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI Institute on January 24, 2008. The information was verified by the guideline developer on February 11, 2008.

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